EXHIBIT B

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,093	10/19/2001	S. Rao Cherukuri	24222-X3	6757

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

EXHIBIT B

Office Action Summary	Application No.	Applicant(s)	
	09/982,093	CHERUKURI, S. RAO	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) *8-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, 132-declaration, amendment, remarks and request for reconsideration, all filed 3/31/06. Receipt is also acknowledged for statement of substance of the interview filed 3/31/06. Claims 1 and 3-24 are pending. Claims 8-24 are withdrawn from consideration. Claims 1 and 3-7 are examined and venlafaxine is elected for examination.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/31/06 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The rejection of claims 1 and 3-7 under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al. (US 6,197,828) is not made in the present office action because the amendment to the claims filed 3/31/06 recite the diameter of the tablet of caplet as from about 1 mm to about 7

mm, and the amount of the lubricant in amount of up to about 5% by weight of the product changing the scope of the claims; and as such the Jerussi reference does not apply since the amount of the lubricant in the compressed tablet of Jerussi is at 29.64 for the 100 mg capsule.

Response to Arguments

Therefore, applicant's argument with respect to the amount of the lubricant is persuasive for the Jerussi reference, and this and other aspects of the arguments are thus moo in view of the withdrawal of the Jerussi.

4. Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sako et al. (US 6,562,375).

The search is extended to amitriptyline, whish is one of the drugs in claim 7 and the rejection follows

Sako discloses stable pharmaceutical composition in a tablet (column 2, lines 21 and 25), the composition comprising yellow or red iron oxide (column 2, lines 13, 14 and 27), polyethylene oxide and hydrophilic base (column 3, lines 1-43; column 4, line 55 to column 5 line 30); the hydrophilic base is one or combination of 2 or more of polyethylene glycol, polyvinylpyrrolidone, sugar alcohols such as D-sorbitol and xylitol, saccharides such as sucrose, maltose, lactulose, D-fructose, dextran and glucose to name a few (column 5, line 58 to column 6 line 12); other additives which include lubricants such as stearic acid, calcium stearate, magnesium stearate to name a few (column 6, line 65 to column 7, line 1); it is noted that Sako discloses that the additives are added as needed (column 6, line 59 and column 7, line 12); the diameter of the tablet in Example 5 is disclosed at 8 mm; Sako specifically discloses that there

are no special restrictions as to the drug used in the formulation but lists amitriptyline hydrochloride antipsychotic drug (column 3, line 63) as one of the drugs.

Regarding the diameter of the tablet or caplet as recited in claim 1, it is noted that 8 mm size of the prior art is very approximate to about 7 mm of claim 1. Thus the difference between Sako and the claims is that Sako permits the artisan to be flexible in including the additives in amounts as needed in the formulation while the claim 1 recites up to about 5% for the lubricant. The calcium stearate and magnesium stearate meet the limitations of the lubricant in claim 1. Amitriptyline meets the limitation of the type of pharmaceuticals in claims 3, 4, 6 and 7 and to the extent that the psychotropic drug is insomnia therapeutic, the amitriptyline, which is one of the anti-depressants recited in claim 7 meets claim 5. Thus, Sako discloses the tablet formulation of the instant invention. Sako does not specifically disclose the amount of the lubricant but suggests to the artisan to use amount of lubricant according to as needed in the formulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation of Sako and to use amount of lubricant or additive in amount necessary for the production of the sustained release preparation and with expectation of producing stable formulation. Thus in the absence of factual evidence, up to 5% lubricant is not patentable over a disclosure directing the use of the lubricant as needed basis.

The 132-declaration:

As it regards the size of the tablet, it is noted that a 3 mm (invention) and a 9 mm size (Jerussi) dosage forms were compared. The claim is directed to from about 1 mm to about 7 mm tablet or caplet diameters. The upper size limit is greater than 7 mm. Ideally, the comparison

should use same sizes for the invention and the prior art in order for the comparison to be equally weighted. The comparison does not also appear to be commensurate with the scope of the claims because, no data points outside of the range are provided. However, the amendment to the claims, which change the scope of the claims have rendered the 132-declaration not applicable to the new prior art applied in view of the amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600